

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Comparative Evaluation of Passive and Active Distraction Techniques on Anxiety Level during Anesthetic Injection among Children of 5 to 10 years of Age.

Protocol summary

Study aim

Comparative Evaluation of Passive and Active Distraction Techniques on Anxiety Level during Anesthetic Injection among Children of 5 to 10 years of Age.

Design

The randomized clinical trial study will be conducted in the form of three parallel groups (two intervention groups and one control group). Since the nature of the intervention was not able to conceal the samples and researchers, blinding will not be applicable in this study. The random function of Excel software will be used for randomization.

Settings and conduct

A sample of 81 children aged 5 to 10 years will be selected from among the children referred to the clinic of Azad University of Dentistry in Tehran and in need of inferior alveolar nerve block. Physiological levels of anxiety will be measured using blood oxygen saturation percentage and pulse rate before and after injection. The intensity of anxiety is measured using the FACES test before and after the injection, and it will be measured using the SEM test during and after the injection.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 5 to 10 years old children, Inferior alveolar nerve block to be mandatory for dental treatment, Obedient children based on Frankel's classification (positive and completely positive) Exclusion criteria: Previous dental experience, Current Systemic disease, Current Medically controlled Psychiatric disease, Hospitalization history

Intervention groups

In the first intervention group, the child actively participates in the fidget spinner game during anesthesia injection. In the second intervention group, the child passively uses headphones during anesthesia injection. In the control group, injections are performed routinely.

Main outcome variables

changes in oxygen saturation percentage; pulse rate changes; FACES index changes; Changes in the SEM index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230829059296N1**

Registration date: **2023-09-06, 1402/06/15**

Registration timing: **prospective**

Last update: **2023-09-06, 1402/06/15**

Update count: **0**

Registration date

2023-09-06, 1402/06/15

Registrant information

Name

Niayesh Ebrahimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8868 9828

Email address

nia78e@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-05, 1402/08/14

Expected recruitment end date

2024-01-04, 1402/10/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative Evaluation of Passive and Active Distraction Techniques on Anxiety Level during Anesthetic Injection among Children of 5 to 10 years of Age.

Public title

Comparative Evaluation of Passive and Active Distraction Techniques on Anxiety Level during Anesthetic Injection among Children of 5 to 10 years of Age.

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

5 to 10 years old children Inferior Alveolar Nerve Block to be mandatory for dental treatment Obedient children based on Frankel's classification (positive and completely positive)

Exclusion criteria:

Previous Dental Experience Current Systemic Disease Current Medically Controlled Psychiatric Disease Hospitalization History

Age

From **5 years** old to **10 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **81**

Randomization (investigator's opinion)

Randomized

Randomization description

In the first stage, samples are selected by convenience sampling. In this way, the samples that met the conditions for entering the study are chosen. In the second stage, the random assignment of samples is done by the random sequence created on the statistical website www.randomizer.org with a ratio of 1:1:1 to three groups of active (fidget spinner game), passive (listening to music), and control so that in each group, 27 people are included.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethical Committee, Deputy of Research , Dental school , Tehran Islamic Azad University

Street address

No:4; 10th Neyestan; Pasdaran Ave

City

Tehran

Province

Tehran

Postal code

1946853314

Approval date

2023-08-05, 1402/05/14

Ethics committee reference number

IR.IAU.DENTAL.REC.1402.092

Health conditions studied**1****Description of health condition studied**

Stress

ICD-10 code

Z73.3

ICD-10 code description

Stress, not elsewhere classified

Primary outcomes**1****Description**

changes in oxygen saturation percentage

Timepoint

Before and immediately after injection.

Method of measurement

A pulse oximeter device on the finger

2**Description**

Pulse rate changes

Timepoint

Before and immediately after injection

Method of measurement

A pulse oximeter device on the finger

3**Description**

changes in FACES index

Timepoint

Before and immediately after injection

Method of measurement

FACES index score

4

Description

Changes in the SEM index

Timepoint

During injection and immediately after injection

Method of measurement

SEM index score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Fidget Spinner game group (active entertainment); Patients in this group are introduced to the fidget spinner before the injection, and they are asked to actively participate in this game during the injection of the inferior alveolar block.

Category

Behavior

2

Description

Intervention group: group listening to music (passive distraction); The child is asked to listen to the music played through headphones. To minimize bias, instead of allowing children to choose their favorite music, a piece of music was played during the injection

Category

Behavior

3

Description

Control group: No special distraction method is used for them during the injection.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental School, Tehran Islamic Azad University

Full name of responsible person

Niayesh Ebrahimi

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No:4, 10th Neyestan, Pasdaran Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Arash Azizi

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Dental School, Tehran Islamic Azad University

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Niayesh Ebrahimi

Position

Dentistry Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available